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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/663,111	09/15/2000	Charles J. Davidson	19601-000320US	3759

7590

08/28/2002

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EXAMINER

PREBILIC, PAUL B

ART UNIT

PAPER NUMBER

3738

DATE MAILED: 08/28/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/663,111

Applicant(s)

DAVIDSON ET AL.

Examiner

Paul B. Prebilio

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 August 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-41 is/are pending in the application.
- 4a) Of the above claim(s) 20-41 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3,5.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

El ction/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-19, drawn to the catheter system, classified in class 623, subclass 1.11.
- II. Claim 20, drawn to the kit, classified in class 206, subclass 438.
- III. Claims 21-41, drawn to method of use, classified in class 606, subclass 108.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because it does not require any of the features set forth in claims 2-19. The subcombination has separate utility such as the repair of branched tube in a blood treatment device.

Inventions I or II and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product as

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claimed could be used in a materially different process such as to treat branched tubing in a blood treatment device or to repair the lymphatic system.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

During a telephone conversation with Sol Sheinbein on June 28, 2002 a provisional election was made **without** traverse to prosecute the invention of Group I, claims 1-19. **Affirmation of this election must be made by applicant in replying to this Office action.** Claims 20-41 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Specification

The disclosure is objected to because of the following informalities:

On page 1 of the specification, the continuing data needs to be updated with the current status of the parent applications.

On page 2, line 10 and page 15, line 32, the publication number does not appear to be correct. Rather, the application number is PCT/US99/00835. The publication date must be later than what is set forth.

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On page 7, line 6 there is no period after the end of the sentence.

Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 7, 8, 10-13, and 15-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Richter et al (US 5,755,734). Richter anticipates the claim language where the catheter body as claimed is element (170) of Richter, side member as claimed is element (171) as claimed, and the stent as claimed is element (110) of Richter; see Figures 15-21 and column 6, line 1 to column 7, line 12.

With regard to claim 7 specifically, either the catheter or the balloon is the sheath as claimed and they flex (i.e. are flexible) into the side vessel; see Figure 16.

With regard to claim 8, the structure is present such that the side member and the branch stent deployment device are the same just used in a different manner at a different time.

With regard to claim 12, Applicant's are directed to see how the balloon tapers on the end.

With regard to claim 13, the stent is fluoroscopically visible material.

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With regard to claims 16 and 17, the balloon inflation lumens are inherently outside the guidewire lumen so that the balloon can be inflated. Otherwise, the catheter would not function as disclosed.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 2-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Richter et al (US 5,755,734) in view of Fischell et al (US 5,669,932). Richter meets the claim language but fails to mark catheters in such a way to indicate location as claimed. However, Fischell teaches that it was known to mark catheters to enable accurate positioning of stents; see the whole document, especially the abstract. Hence, it would have been obvious to make the Richter stent in a similar fashion in order to enable more accurate placement of the stents thereof.

Claims 9 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Richter et al (US 5,755,734) in view of Fischell et al (US 5,749,825).

With regard to claim 9, Richter meets the claim language except for the connector of the side guidewire and catheter. However, Fischell teaches that it was known to connect side guidewires to balloon catheters in order to aid in the insertion and expansion of side stents; see the whole document, especially Figures 3 to 5. Hence, it is the Examiner's position that it would have been obvious to connect the side

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guidewire, catheter, and stent of Richter to the main vessel catheter (170) for the same reasons that Fischell does the same and in order to afford greater stability during insertion of the system of Richter.

With regard to claim 19, Richter fails to disclose the attached and unattached portions of the stent and the length of the detached portion as claimed. However, Fischell teaches that it was known to have an attached and unattached portion of a side guidewire and stent location device where the unattached portion is only on the end. The length of the unattached is not disclosed, but the claimed range is broad enough that it would have been rendered obvious by Fischell and because it does not result in some unexpected result. Hence, it is the Examiner's position that the presence of attached portion and unattached portions of the claimed length would have been considered clearly obvious to an ordinary artisan for the same reasons that Fischell does the same with the length of unattached portions being obvious.

Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Richter et al (US 5,755,734) in view of Davila et al (US 5,851,464). Richter meets the claim language except for the pebax and graphite catheter as claimed. However, Davila teaches that it was known to make catheters out of pebax and graphite; see column 3, lines 8-32. Hence, it is the Examiner's position that it would have been obvious to make the catheters of Richter out of pebax and graphite for the same reasons that Davila does the same and in order to promote sliding between the catheter and guidewire.

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Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 USC 102 or 35 USC 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is respectfully requested to provide a list of all copending applications that set forth similar subject matter to the present claims. A copy of such copending claims is respectfully requested in response to this Office action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul Prebilic whose telephone number is (703) 308-2905. The examiner can normally be reached on Monday-Thursday from 6:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached on (703) 308-2111. The fax phone number for this Technology Center is (703) 872-9301.

Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 3700 receptionist whose telephone number is (703) 308-0858.



Paul Prebilic
Primary Examiner
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